



5. Exhibit A is a date-redacted copy of an invention record disclosure signed by Vladimir Mitelberg and me. Exhibit A reports on work performed by us and/or under our direction and control in the United States of America prior to June 4, 1999, in connection with making embolic coils for occluding the vasculature of a patient, which devices were made and reduced to practice before June 4, 1999.

6. With respect to Exhibit A (the invention record) referred to in paragraph 5 above, the photographs set forth in the last page of this invention record were taken by me of the roughened coils prior to submitting them for evaluation. The page having the number 028122 shows service requests. The picture on the bottom is a service request in which the coils were submitted for evaluation. Four photomicrographs were taken as indicated by the middle box and these four microphotographs were the results of the service requests. These photomicrographs are on the page of Exhibit A following the service requests. All of these photographs and service requests were taken and made prior to June 4, 1999.

7. Exhibit B are date-redacted copies of experiments performed on baboons, in connection with occluding the vasculature of the baboons, which experiments were performed before June 4, 1999.

8. The work referred in paragraph 7 above, included ex-vivo tests outside of the body using the baboon. A silicone tube was connected to the artery of the baboon. Blood flow was through the silicone tube and back to the baboon. In the silicone tube, aneurysms were formed on the tube itself. A delivery catheter was used to place roughened embolic coils inside of the aneurysms, with the help of a pusher mechanism. Live blood was run through the system and radioactive platelets accumulated on the

coils. The coils used were textured 5 mm. complex coils. By using a gamma camera imager, the radioactivity was measured. Non-textured coils were also used. It was found that there were greater amount of platelets on the roughened coils then on the non-roughened coils. From these experiments we were able to conclude that the introduction of the textured coils in the aneurysm would enhance platelet adhesion.

9. In view of my experience in biomedical engineering (including embolization devices) prior to June 4, 1999, I was confident that the vasculature of a patient could be successfully occluded by providing a plurality of embolic coils having a proximal portion that is held by the detachment portion and a distal portion, with the proximal portion that is held by the detachment portion being relatively smooth and the distal portion having a relatively textured surface. I found that the textured surface provides improved platelet adhesion compared to a non-textured surface, to promote clotting. As a result of the experiments, I was confident that the embolization device having a roughened surface was suitable for placement in a catheter for being conventionally implanted with an introducer having a detachment portion to provide improved platelet adhesion compared to a non-textured surface, to promote clotting. Accordingly, in my view, the invention was reduced to practice on a date prior to June 4, 1999, because I was confident that clinical versions of the prototype could be sterilized and clinically used with success to embolize aneurysms in patients.

10. I hereby declare that all statements made herein and of my own knowledge are true, and that all statements made on information and belief are believed to be true; and I further declare that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or

imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or patent issued therefrom.

Date: 5/11/04

  
\_\_\_\_\_  
Donald K. Jones

PATENT

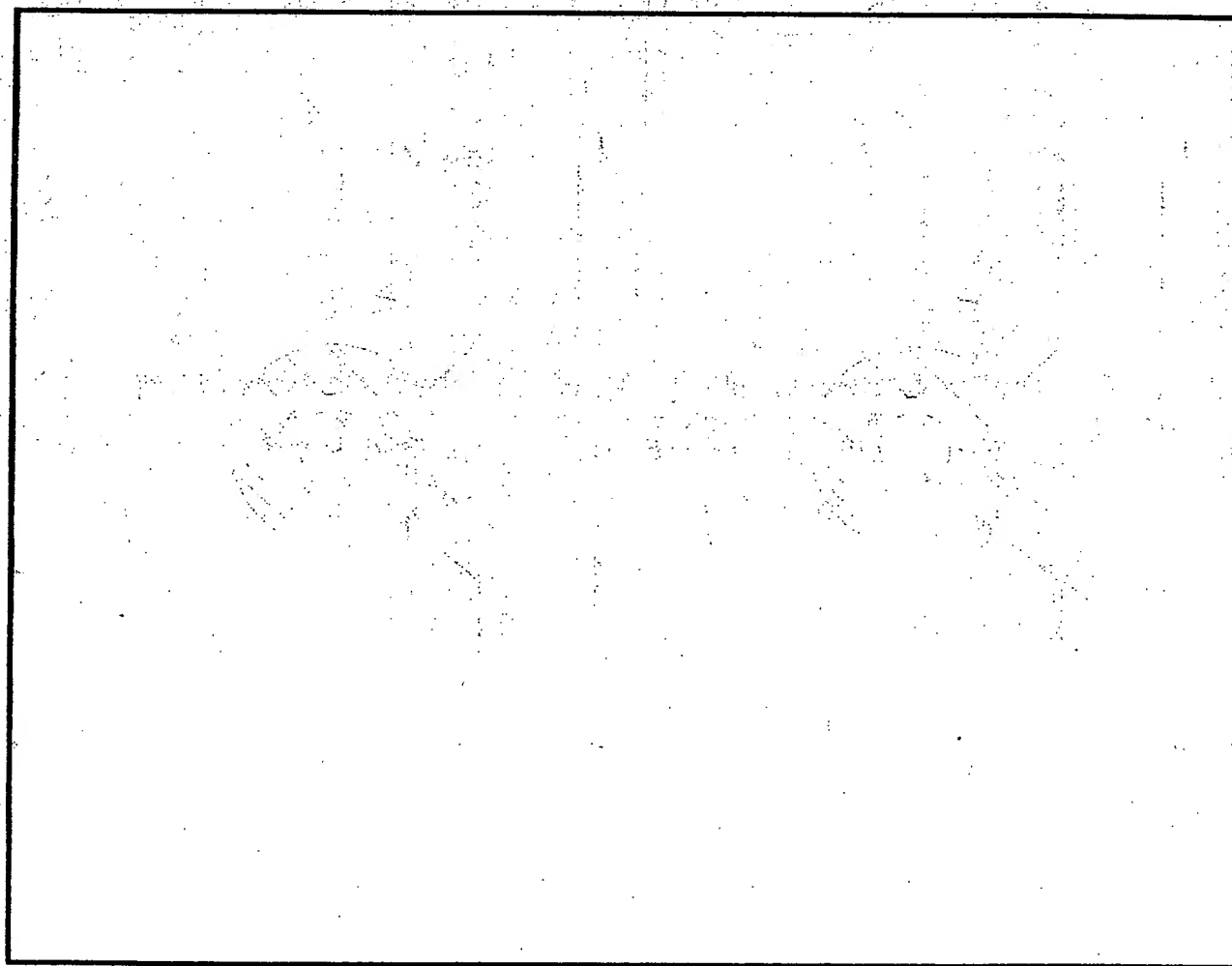
**Cordis**

DEPARTMENT

00/140

**DESCRIPTIVE TITLE: Coil Surface Modification**

- I. **INSTRUCTIONS:** This form should be typed, except for the signatures and dates. Disclose only one invention on this Invention Disclosure form, and complete the entire form as fully as possible. Forward the completed form to the Legal Department, signed and dated by all inventors and two witnesses. Refer to this Invention Disclosure by the number assigned to it when receipt is acknowledged. Attach additional sheets if more space is required. Each original piece of paper must be signed and dated by every inventor and by each witness.
- II. **ILLUSTRATION:** *Include a drawing, sketch, photograph, flow chart, or preferably an engineering quality printout of the invention.*



Name & Signature of Inventor(s):

Date

Witnesses

Date

V. H. S.  
Donald E. Jones

E. A. S.  
W. H. S.

**EXHIBIT A**

**III. EXPLANATION OF INVENTION:** *Describe the invention completely, including all essential elements.*

The invention is a surface modified embolization coil. The surface has been texture by abrasion or "sand blasting". Fifty-micron diameter alumina particles were used to texture the surface of the platinum tungsten wire used to form the coils. It is believed that the textured surface provides improved platelet adhesion thus promoting clotting and subsequent endothelialization. SEM micrographs and optical pictures of the textured vs. non-textured are attached. Testing using radiolabeled platelets was conducted to evaluate an ex vivo aneurysm model. In the model, aneurysms treated with textured coils were compared to aneurysms treated with non-textured coils. The textured coils showed an increase in the platelet deposition of about 50% over the non-textured coils.

**IV. NOVEL FEATURES AND ADVANTAGES:** *What is new that was not previously known, and why is this important.*

Other surface modification techniques such as coating or ion implantation require expensive and elaborate equipment to modify the coils which add an additional component. This method does not impart any new materials to the coil that would require new biocompatibility testing and can be done inexpensively.

**V. MODIFICATIONS:** *Describe all possible modifications or alternate embodiments.***VI. RELATED DOCUMENTS:** *List all known relevant art references (patents, publications, commercially available products, etc.). Please supply copies of the documents, if available.*

Patents:

Publications:

Signature of Inventor(s):

Date:

Witnesses:

Date:

V. Hing

Wanda L. Green

E. Hing  
Wanda L. Green

VII. INVENTORS:

DEPARTMENT

First Inventor's Full name (Please type:)

Donald K. Jones

Signature: \_\_\_\_\_

*Donald K. Jones*

Date: \_\_\_\_\_

Second Inventor's Full Name (Please type:)

Vladimir Mittelberg

Signature: \_\_\_\_\_

*V. Mittelberg*

Date: \_\_\_\_\_

VIII. WITNESSES: This invention was disclosed to and understood by:

Full Name of First Witness (Please type: *Eric Cheng*)

Signature: \_\_\_\_\_

*Eric Cheng*

Date: \_\_\_\_\_

Full Name of Second Witness (Please type:)

*Boles Shkolnik*

Signature: \_\_\_\_\_

*Boles Shkolnik*

Date: \_\_\_\_\_

IX. ADDITIONAL INFORMATION:

Invention is recorded on page(s): \_\_\_\_\_ of Notebook No.: \_\_\_\_\_ dated: \_\_\_\_\_

Earliest date: \_\_\_\_\_ and place: CES where inventors first  
thought of the present invention.

First written description (date and present location): \_\_\_\_\_

First sketch of the invention (date and present location): \_\_\_\_\_

Earliest date: \_\_\_\_\_ and place: \_\_\_\_\_ where first operating  
model  
was completed.

Present location of model: \_\_\_\_\_

Earliest date of use of the invention (actual or contemplated): \_\_\_\_\_

Earliest shipping date (actual or contemplated): \_\_\_\_\_

## Service Request

Job number, assigned by  
supplying organization

32 02 7

R qu for	To	CPQA, EML LAB		
	From (organization)	CES		
	Location	PETER GUINONES x 81020		
	For information contact	81676		
	Description of request	PLEASE PROVIDE SEM PHOTOS OF SURFACE OF COILS PROVIDED FOR ROUGHNESS EVALUATION.		
	Requested by	P. Guinones		
	Approved by			
	Date			
	Date			

S up plier	Date received			
	Labor cost			
	Material cost			
	Purchased Materials, services or equipment required	Witchard 92071-46		
	Completion date			
	Comments	Electron optical micrographs were taken of each sample at low & high magnifications to show surface roughness conditions.		
	Estimate by	John Dault		
	Date	1 / 1		

A pp roval	Cost and completion date accepted by requestor			
	Signature			
	Date			
	Comment			
	Supplier acceptance by	B. P.		
	Date	1 / 1		



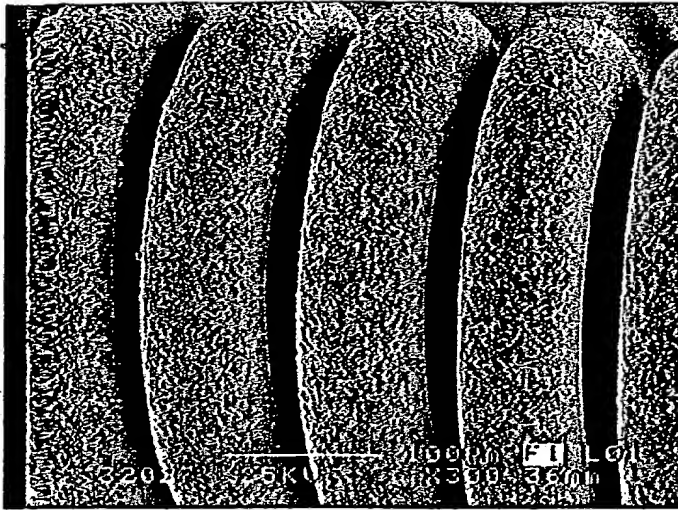


Figure 1-(233x) Sample with rough surface

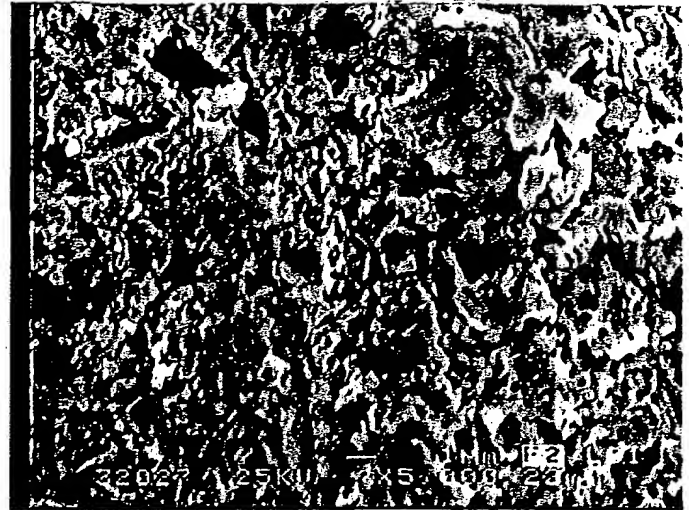


Figure 2-(3880x) Sample with rough surface

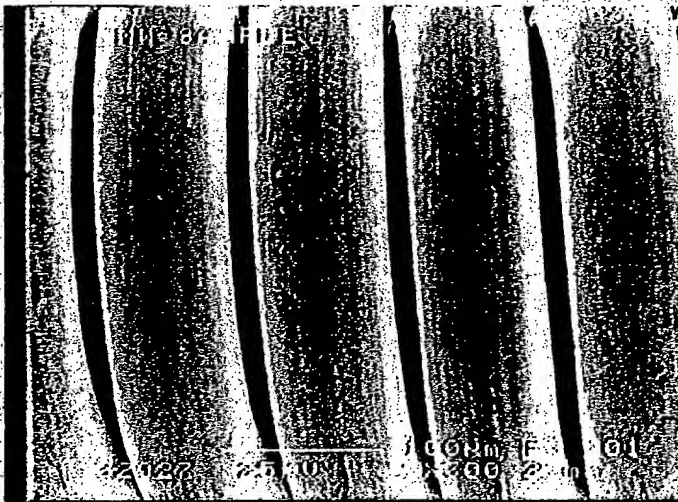


Figure 3-(233x) Sample "MW" with smooth surface.

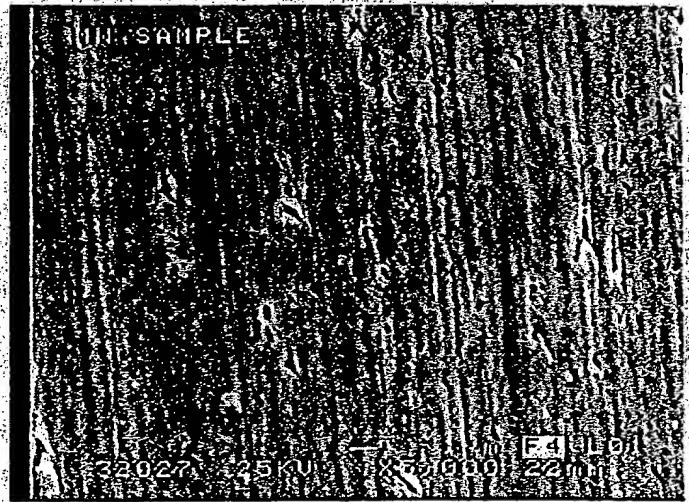


Figure 4-(3880x) Sample "MW" with smooth surface.

*David K. Price*

40 X Mag

.003" H<sub>2</sub>O

5mm  
Complex  
(20-100µ)

No Surface Treatment



PAT

DEPAR

DXP

40 X Mag

.003" H<sub>2</sub>O

5mm  
Complex  
(20-100µ)

Surface Treatment



20-100µ

Surface Abraded using AumBRADe - 5 3113  
50 micron blend of Al<sub>2</sub>O<sub>3</sub> (Part No. 40105)

DXP

Baboon B384right  
Date

Computer  
Data Partitl n  
Camera  
ROI (device)  
Window  
Energy > 172  
Collimator > low  
Matrix  
128 > byte

### Study Description

Aneurysm Run #7 textured 5mm dlm. complex  
coils. Tail from Aneu. #1 extended 130mm.  
Tail from Aneu. #2 extended 180mm

iodine

Remarks

Pit Cnt Pre	314
Pit Cnt Post	267
WBC	8.7
Hct Pre	41.10%
Hct Post	38.00%
Flow (ml/min)	100 clamp

Whole Blood	171188
Plasma	21908
Fraction	92.5%
Free	7.5%
Volume (cc)	3

Blood Std CPM	2285
Bkg CPM	291
Bkgd CPM 1	1994
CPM in-plts	1843.696
CPM/ml in-plts	614.5654
FINIAL	0.000511

ROI ROI

#1	ROI	ROI	CPM	CPM bkg	Thrombus	Standard	Pits x10 <sup>6</sup>
Time							
Min							
5	196	167	29	0.000511	0.01		
10	197	166.00	31	0.000511	0.02		
15	285	266.00	19	0.000511	0.01		
20	356	428.00	-72	0.000511	-0.04		
25	609	645.00	-36	0.000511	-0.02		
30	870	849.00	21	0.000511	0.01		
35	1100	1140.00	-40	0.000511	-0.02		
40	1340	1430.00	-90	0.000511	-0.05		
45	1540	1570.00	-72	0.000511	-0.04		
50	1840	1810.00	30	0.000511	0.02		
55	2020	1850.00	170	0.000511	0.09		
60	2130	1940.00	190	0.000511	0.10		
65	2220	2080.00	140	0.000511	0.07		
70	2170	1960.00	210	0.000511	0.11		
75	1990	1890.00	100	0.000511	0.05		
80	1950	1750.00	200	0.000511	0.10		
85	1790	1730.00	60	0.000511	0.03		
90	1730	1550.00	180	0.000511	0.09		
95	1750	1670.00	80	0.000511	0.04		
100	1780	1610.00	170	0.000511	0.09		
105	1730	1600.00	130	0.000511	0.07		
110	1730	1540.00	190	0.000511	0.10		
115	1680	1460.00	220	0.000511	0.11		
120	1710	1470.00	240	0.000511	0.12		
125	1700	1470.00	230	0.000511	0.12		
130	1750	1370	380	0.000511	0.19		
135	1720	1440	280	0.000511	0.14		
140	1740	1460	280	0.000511	0.14		
145	1850	1310	540	0.000511	0.28		
150	1730	1390	340	0.000511	0.17		

Time	CPM	CPM bkg	Thrombus	Standard	Pits x10 <sup>9</sup>
155	1800	1250	550.00	0.000511	0.28
160	1800	1400	400.00	0.000511	0.20
165	1700	1260	440.00	0.000511	0.22
170	1600	1250	350.00	0.000511	0.18
175	1770	1270	500.00	0.000511	0.28
180	1650	1250	400.00	0.000511	0.20
185	1640	1270	370.00	0.000511	0.19
190	1730	1230	500.00	0.000511	0.26
195	1740	1240	500.00	0.000511	0.28
200	1620	1270	350.00	0.000511	0.18
205	1630	1230	400.00	0.000511	0.20
210	1720	1210	510.00	0.000511	0.28
215	1650	1230	420.00	0.000511	0.21
220	1690	1250	440.00	0.000511	0.22
225	1640	1120	520.00	0.000511	0.27
230	1580	1160	420.00	0.000511	0.21
235	1720	1150	570.00	0.000511	0.28
240	1520	1080	440.00	0.000511	0.22





Baboon 374P:left	Computer
Date	Data Partition
Study Description	Camera
	ROI (device)
Aneurysm Run #1 untextured 5mm dlm. complex colls.	Window
Tail from Aneu. #1 stopped 1.25" from aneu. #2.	Energy
Tail from Aneu.#2 extended 16"	

**flow stopped at 1hr 25min - shunt was flushed**

Remarks

TIm	ROI		43x48	CPM	ROI	CPM	bkg	Thrombus	Standard	Plts x10 <sup>9</sup>
	Min	Max								
5	145	103	42.00	0.000689	0.03					
10	162	165	-3.00	0.000689	0.00					
15	229	194	35.00	0.000689	0.02					
20	240	237	3.00	0.000689	0.00					
25	323	242	81.00	0.000689	0.06					
30	331	307	24.00	0.000689	0.02					
35	398	344	54.00	0.000689	0.04					
40	444	401	43.00	0.000689	0.03					
45	506	396	110.00	0.000689	0.08					
50	538	406	132.00	0.000689	0.09					
55	575	461	114.00	0.000689	0.08					
60	633	478	155.00	0.000689	0.11					
65	668	486	182.00	0.000689	0.13					
70	660	512	148.00	0.000689	0.10					
75	800	563	237.00	0.000689	0.16					
80	814	528	286.00	0.000689	0.20					
85	883	644	239.00	0.000689	0.16					
90	938	616	322.00	0.000689	0.22					
95	924	650	274.00	0.000689	0.19					
100	958	688	270.00	0.000689	0.19					
105	922	694	228.00	0.000689	0.16					
110	964	674	280.00	0.000689	0.20					
115	986	684	322.00	0.000689	0.22					
120	959	652	307.00	0.000689	0.21					
125	897	666	231.00	0.000689	0.16					
130	872	660	212.00	0.000689	0.15					
135	996	700	296.00	0.000689	0.20					
140	1010	686	324.00	0.000689	0.22					
145	1030	754	276.00	0.000689	0.19					
150	986	704	282.00	0.000689	0.19					

A3	
A341	
GE	
8 x 10	
15%	
172	
247	
low	
med	
word	
byte	

Plt Cnt Pre	295
Plt Cnt Post	204
WBC	11.5
Hct Pre	45.40%
Hct Post	42.10%
Flow (ml/min)	100/clamp

Whole Blood	121465
Plasma	16014
Fraction	92.8%
Free	7.2%
Volume (cc)	3

Blood Std CPM	1672
Bkg CPM	291
Bkgd CPM 1	1381
CPM In-pits	1281,589
CPM/ml In-pits	427.1963
FINAL	0.000691

ROI

Time CPM

Min	CPM	CPM:bkg	Thrombus	Standard	Pits $\times 10^3$
155	1070	804	266.00	0.000689	0.18
160	1120	756	364.00	0.000689	0.25
165	1140	796	344.00	0.000689	0.24
170	1210	760	450.00	0.000689	0.31
175	1160	800	360.00	0.000689	0.26
180	1130	804	326.00	0.000689	0.22
185	1210	846	364.00	0.000689	0.25
190	1250	842	408.00	0.000689	0.28
195	1270	900	370.00	0.000689	0.26
200	1270	928	342.00	0.000689	0.24
205	1350	948	402.00	0.000689	0.28
210	1380	984	396.00	0.000689	0.27
215	1330	1020	310.00	0.000689	0.21
220	1310	1060	250.00	0.000689	0.17
225	1310	1080	230.00	0.000689	0.16
230	1300	1170	130.00	0.000689	0.09
235	1420	1130	280.00	0.000689	0.20
240	1280	1190	100.00	0.000689	0.07

Whole Blood	121465
Plasma	16014

Free	7.2%
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Volume (cc) 3

M-1	1381	.....
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427:1963

[illegible]